

# **EXHIBIT A**

# **COMPLAINT ACTION COVER SHEET**

DOCKET NO. (S)

04-1706

**State Court of Massachusetts  
Superior Court Department  
County: MIDDLESEX**



Plaintiff: Johnson, et al.

DEFENDANT(S)

Indevus Pharmaceuticals, Inc., f/k/a Interneuron Pharmaceuticals  
Inc., et als

ATTORNEY FIRM, ADDRESS AND TELEPHONE (617) 720-1333  
 C. Strauss, Esq. (BBO#546253), Marilyn T. McGoldrick, Esq.  
 (BBO#561766) THORNTON & NAUMES, LLP,  
 100 Summer St., 30th fl., Boston, MA 02110  
 Baron & Budd, 3102 Oak Lawn Avenue, Ste. 1100, Dallas, TX 75219  
 Board of Bar Overseers number:

ATTORNEY (if known)

## **Origin code and track designation**

Place and x in one box only:

☒ 1.FO1 Original Complaint☐ 2.FO2 Removal to Sup.Ct. C.231, s.104  
(Before trial) (F)☐ 3.FO3 Retransfer to Sup.Ct.C.231,s.102C(X)☐ 4.F04 District Court Appeal c.231,s.97 & 104  
(After trial) (X)☐ 5.F05 Reactivated after rescript; relief  
from judgment/Order (Mass.R.Civ.P.60) (X)☐ 6.E10 Summary Process Appeal (X)

## **TYPE OF ACTION AND TRACK DESIGNATION (See Reverse Side)**

CODE NO. TYPE OF ACTION (specify) TRACK IS THIS A JURY CASE?

B05 Products Liability ( A ) ( x ) Yes ( ) No

The following is a full, itemized and detailed statement of the facts on which plaintiff relies to determine money damages. For this form, disregard double or treble damage claims; indicate single damages only.

## **TORT CLAIMS**

(Attach additional sheets as necessary)

### **A. Documented medical expenses to date:**

- |  |                   |
|--|-------------------|
| 1. Total hospital expenses .....         | \$..see attached. |
| 2. Total Doctor expenses .....           | \$..see attached. |
| 3. Total chiropractic expenses .....     | \$..see attached. |
| 4. Total physical therapy expenses ..... | \$..see attached. |
| 5. Total other expenses (describe) ..... | \$..see attached. |

Subtotal \$..see attached..

### **B. Documented lost wages and compensation to date**

C. Documented property damages to date .....

D. Reasonably anticipated future medical and hospital expenses .....

E. Reasonably anticipated lost wages .....

F. Other documented items of damages (describe) .....

\$..see attached..

### **G. Brief description of plaintiff's injury, including nature and extent of injury (describe)**

Plaintiff suffers from an asbestos-related disease arising out of his exposure to asbestos and asbestos-containing products mined, milled, manufactured, fabricated, supplied and/or sold by defendants.

\$..see attached..

TOTAL \$..2,000,000.00.

## **CONTRACT CLAIMS**

(Attach additional sheets as necessary)

Provide a detailed description of claim(s):

TOTAL \$.....

PLEASE IDENTIFY, BY CASE NUMBER, NAME AND COUNTY, ANY RELATED ACTION PENDING IN THE SUPERIOR COURT DEPARTMENT

Eastern Counties Massachusetts Asbestos Litigation Docket

"I hereby certify that I have complied with the requirements of Rule 5 of the Supreme Judicial Court Uniform Rules on Dispute Resolution (SJC Rule 1:18) requiring that I provide my clients with information about court-connected dispute resolution services and discuss with them the advantages and disadvantages of the various methods."

Signature of Attorney of Record

DATE: 4/21/04

Esq.

# CIVIL ACTION COVER SHEET INSTRUCTIONS

## SELECT CATEGORY THAT BEST DESCRIBES YOUR CASE

CONTRACT			REAL PROPERTY			MISCELLANEOUS		
A01	Services, labor and materials	(F)	C01	Land taking (eminent domain)	(F)	E02	Appeal from administrative Agency G.L. c. 30A	(X)
A02	Goods sold and delivered	(F)	C02	Zoning Appeal, G.L. c.40A	(F)	E03	Action against Commonwealth Municipality, G.L. c.258	(A)
A03	Commercial Paper	(F)	C03	Dispute concerning title	(F)	E05	All Arbitration	(X)
A08	Sale or lease of real estate	(F)	C04	Foreclosure of mortgage	(X)	E07	c.112,s.12S (Mary Moe)	(X)
A12	Construction Dispute	(A)	C05	Condominium lien and charges	(X)	E08	Appointment of Receiver	(X)
A99	Other (Specify)	(F)	C99	Other (Specify)	(F)	E09	General contractor bond, G.L. c.149,s.29,29a	(A)
TORT			EQUITABLE REMEDIES			E11	Workman's Compensation	(X)
B03	Motor Vehicle negligence-personal injury/property damage	(F)	D01	Specific performance of contract	(A)	E14	Chapter 123A Petition-SDP	(X)
B04	Other negligence-personal injury/property damage	(F)	D02	Reach and Apply	(F)	E15	Abuse Petition, G.L.c.209A	(X)
B05	Products Liability	(A)	D06	Contribution or Indemnification	(F)	E16	Auto Surcharge Appeal	(X)
B06	Malpractice-medical	(A)	D07	Imposition of Trust	(A)	E17	Civil Rights Act, G.L.c.12,s.11H	(A)
B07	Malpractice-other(Specify)	(A)	D08	Minority Stockholder's Suit	(A)	E18	Foreign Discovery proceeding	(X)
B08	Wrongful death,G.L.c.229,s2A	(A)	D10	Accounting	(A)	E96	Prisoner Cases	(F)
B15	Defamation (Libel-Slander)	(A)	D12	Dissolution of Partnership	(F)	E97	Prisoner Habeas Corpus	(X)
B19	Asbestos	(A)	D13	Declaratory Judgment G.L.c.231A	(A)	E99	Other (Specify)	(X)
B20	Personal Injury-Slip&Fall	(F)	D99	Other (Specify)	(F)			
B21	Environmental	(A)						
B22	Employment Discrimination	(F)						
B99	Other (Specify)	(F)						

TRANSFER YOUR SELECTION TO THE FACE SHEET.

EXAMPLE:

CODE NO.	TYPE OF ACTION (SPECIFY)	TRACK	IS THIS A JURY CASE?
B03	Motor Vehicle Negligence-Personal Injury	(F)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

## SUPERIOR COURT RULE 29

**DUTY OF THE PLAINTIFF.** The plaintiff or his/her counsel shall set forth, on the face sheet (or attach additional sheets as necessary), a statement specifying in full and itemized detail the facts upon which the plaintiff then relies as constituting money damages. A copy of such civil action cover sheet, including the statement as to the damages, shall be served on the defendant together with the complaint. If a statement of money damages, where appropriate is not filed, the Clerk-Magistrate shall transfer the action as provided in Rule 29(5)(C).

**DUTY OF THE DEFENDANT.** Should the defendant believe the statement of damages filed by the plaintiff in any respect inadequate, he or his counsel may file with the answer a statement specifying in reasonable detail the potential damages which may result should the plaintiff prevail. Such statement, if any, shall be served with the answer.

**A CIVIL ACTION COVER SHEET MUST BE FILED WITH EACH COMPLAINT, BUFF COLOR PAPER.**

**FAILURE TO COMPLETE THIS COVER SHEET THOROUGHLY AND ACCURATELY  
MAY RESULT IN DISMISSAL OF THIS ACTION.**

**Plaintiffs' Attachment to Civil Action Cover Sheet:**  
**Linda Marlene Johnson, et al.**  
**DOCKET NO. 00-**

Plaintiffs, Linda Marlene Johnson, et. al, suffer from valvular heart disease and/or primary pulmonary hypertension. Although they have each incurred substantial doctor, medical, hospital, clinic, therapy and rehabilitative expenses as a result of their treatment for their injuries, plaintiffs have no documentation of these expenses at this time. However, plaintiffs expect that expenses relating to their injuries exceeded \$500,000. Plaintiffs have requested copies of medical bills which should enable them to more accurately document the medical expenses. Future medical expenses are expected to exceed \$500,000.

As a result of the tortious conduct of the defendants, plaintiffs have been damaged to the extent that they will suffer a dramatic reduction in their life expectancy, experience great mental and physical pain and suffering and suffer an impairment in their enjoyment of life, and lost earning capacity. Plaintiffs estimate that these damages exceed \$500,000.

As a result of their injuries, plaintiffs, Joe Sheff, Sheryl Van Slice, Sharon E. Gabrich, Theodore Dale Minzey and Armando Ochoa, have suffered and continue to suffer a corresponding loss of consortium with their spouse and have suffered and continue to suffer a loss of their spouse's services, society and affection. Plaintiffs estimate that these damages exceed \$500,000.

Plaintiffs estimate that the total damages suffered by them will far exceed \$2,000,000 in actual damages plus punitive damages.

Plaintiffs reserve the right to amend or supplement this statement.



## COMMONWEALTH OF MASSACHUSETTS

EASTERN COUNTIES, SS.  
MIDDLESEX, SS.

SUPERIOR COURT

**IN RE MASSACHUSETTS STATE COURT DIET DRUG  
LITIGATION**

Linda Marlene Johnson, Carla S. Alvanchi, Vickie L. Beinlich, Cynthia D. Cargile, Theresa S. Dresher, Terry Robert Gabrich, Sr. and Sharon E. Gabrich; Robert John Golias; Camille Denice Johnson; Edith A. Guffey; Lisa Henkel; Sherry L. Jackson; Linda S. Kennelly; Janice A. Lukacinsky and Sheryl Van Sice; Sally Jane Minzey and Theordore Dale Minzey; Irma Ochoa and Armando Ochoa; Teresa Shuff and Joe Shuff; Bonnie L. Tacy; and, Victoria Vance,

Plaintiffs.

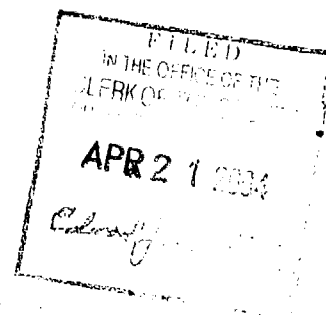
v.

Indevus Pharmaceuticals, Inc., F/K/A Interneuron Pharmaceuticals, Inc.; Wyeth, Inc., F/K/A American Home Products Corporation; Wyeth Pharmaceuticals, Inc F/K/A Wyeth-Ayerst Pharmaceuticals, Inc., A Division Of American Home Products Corporation; and Boehringer Ingelheim Pharmaceuticals, Inc.; Robert R. DeCapua; Justin D. Crum; Bernice J. Menzies; Michelle L. Carner; Larry D. Bayliff; Gerald E. Lubben; Joseph Schrei; Gail S. Rasak, Marlo F. Ponos (a/k/a/ Marlo F. Tate); Michael D. Zell; Gregory Fountain; Mary Ann Roberts; Lyn A. Adanich; Kathleen A. Welsh; Ronald L. Duemler; Dennis M. Thimm; Lance E. Reno; Cynthia M. Cowgill; Timothy S. Circle; Donell N. Henthorne; Melody Phillips-Williams; Steve Sneider; Richard A. Dilibero; Thomas M. Duggan; Jennifer Hetherington; Joanne M. Izykowski; Zoanne H. Pokriefka; Joseph DiFrancesco; Hope Tileston; Thomas A. Wiehn; Lisa M. Birken (a/k/a Lisa Greenbaum); Shonda S. Shores (a/k/a Shonda S. Kim); Christian K. Miner; Kimberly Ann Owen; Mary M. Bodenhamer; Alicia I. McDougal; Shannon O. Sage; and, John Doe.

Defendants.

Civil Action  
No.

04-1706

COMPLAINT

04/21/04 15:55#0000 6247 CLERK E

230	240.00
CIVIL	5520.00
SURCHARGE	15.00
SECC	20.00
041706 #	
SUBTTL	5555.00
TOTAL	<b>5555.00</b>
CHECK	5555.00

Plaintiffs, as named herein (collectively referred to as “Plaintiffs”), by and through their undersigned counsel, sue Defendants, Indevus Pharmaceuticals, Inc., f/k/a Interneuron Pharmaceuticals, Inc.; Wyeth, Inc. f/k/a American Home Products Corporation; Wyeth Pharmaceuticals, Inc. f/k/a WyethAyerst Pharmaceuticals, Inc., a Division of American Home Products Corporation; and Boehringer Ingelheim Pharmaceuticals, Inc.; Robert R. DeCapua; Justin D. Crum; Bernice J. Menzies; Michelle L. Carner; Larry D. Bayliff; Gerald E. Lubben; Joseph Schrei; Gail S. Rasak; Marlo F. Ponos (a/k/a/ Marlo F. Tate); Michael D. Zell; Gregory Fountain; Mary Ann Roberts; Lyn A. Adanich; Kathleen A. Welsh; Ronald L. Duemler; Dennis M. Thimm; Lance E. Reno; Cynthia M. Cowgill; Timothy S. Circle; Donell N. Henthorne; Melody Phillips-Williams; Steve Sneider; Richard A. Dilibero; Thomas M. Duggan; Jennifer Hetherington; Joanne M. Izykowski; Zoanne H. Pokriefka; Joseph DiFrancesco; Hope Tileston; Thomas A. Wiehn; Lisa M. Birken; Lisa Greenbaum; Shonda S. Shores (a/k/a Shonda S. Kim); Christian K. Miner; Kimberly Ann Owen; Mary M. Bodenhamer; Alicia I. McDougal; Shannon O. Sage; and John Doe; and upon information and belief, allege as follows:

### **Plaintiffs’ Allegations**

1. Plaintiffs file this action against the named Defendants for injuries, including but not limited to valvular heart disease (“VHD”), secondary pulmonary hypertension, and other associated injuries suffered by Plaintiffs as a result of their ingestion of the defective and dangerous pharmaceutical diet drugs Redux™ and Pondimin® (“Diet Drugs”) which were researched, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged

and/or sold by Defendants, Indevus Pharmaceuticals, Inc., f/k/a Interneuron Pharmaceuticals, Inc. ("Interneuron" or "Defendant"); Wyeth, Inc. f/k/a American Home Products Corporation ("Wyeth Defendant" or "Defendant"); Wyeth Pharmaceuticals, Inc. f/k/a Wyeth-Ayerst Pharmaceuticals, Inc. ("Wyeth Defendant" or "Defendant"); Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer" or "Defendants"); Robert R. DeCapua; Justin D. Crum; Bernice J. Menzies; Michelle L. Carner; Larry D. Bayliff; Gerald E. Lubben; Joseph Schrei; Gail S. Rasak; Marlo F. Ponos (a/k/a/ Marlo F. Tate); Michael D. Zell; Gregory Fountain; Mary Ann Roberts; Lyn A. Adanich; Kathleen A. Welsh; Ronald L. Duemler; Dennis M. Thimm; Lance E. Reno; Cynthia M. Cowgill; Timothy S. Circle; Donell N. Henthorne; Melody Phillips-Williams; Steve Sneider; Richard A. Dilibero; Thomas M. Duggan; Jennifer Hetherington; Joanne M. Izykowski; Zoanne H. Pokriefka; Joseph DiFrancesco; Hope Tileston; Thomas A. Wiehn; Lisa M. Birken; Lisa Greenbaum; Shonda S. Shores (a/k/a Shonda S. Kim); Christian K. Miner; Kimberly Ann Owen; Mary M. Bodenhamer; Alicia I. McDougal; Shannon O. Sage; and John Doc, as more fully detailed herein below.

2. This action is brought on behalf of the following Plaintiffs each of whom is suffering from VHD as a result of the ingestion, consumption and use of the Diet Drugs and each of whom is at risk of developing or is already suffering from secondary pulmonary hypertension and other related conditions as a direct and proximate result of said ingestion, consumption and use:

a. Plaintiff Carla S. Alvanchi is a citizen and resident of Garland, TX who is suffering from VHD as a result of the ingestion of the Diet Drugs;

b. Plaintiff Vickie L. Beinlich is a citizen and resident of Lincolnshire, IL who is suffering from VHD as a result of the ingestion of the Diet Drugs;

c. Plaintiff Cynthia D. Cargile is a citizen and resident of Canton, MI who is suffering from VHD as a result of the ingestion of the Diet Drugs;

d. Plaintiff Theresa S. Drescher is a citizen and resident of Neosho, MO who is suffering from VHD as a result of the ingestion of the Diet Drugs;

e. Plaintiff Terry Robert Gabrich Sr. is a citizen and resident of Gahanna, OH who is suffering from VHD as a result of the ingestion of the Diet Drugs;

f. Plaintiff Robert John Golias is a citizen and resident of Cleveland, OH who is suffering from VHD as a result of the ingestion of the Diet Drugs;

g. Plaintiff Camille Denice Johnson is a citizen and resident of Muskegon, MI who is suffering from VHD as a result of the ingestion of the Diet Drugs;

h. Plaintiff Edith A. Guffey is a citizen and resident of Solon, OH who is suffering from VHD as a result of the ingestion of the Diet Drugs;

i. Plaintiff Lisa Henkel is a citizen and resident of Terrace Park, OH who is suffering from VHD as a result of the ingestion of the Diet Drugs;

j. Plaintiff Sherry L. Jackson is a citizen and resident of Mineral Wells, WV who is suffering from VHD as a result of the ingestion of the Diet Drugs;

k. Plaintiff Linda Marlene Johnson is a citizen and resident of Tyler, TX who is suffering from VHD as a result of the ingestion of the Diet Drugs;

l. Plaintiff Linda S. Kennelly is a citizen and resident of Chepachet, RI who is suffering from VHD as a result of the ingestion of the Diet Drugs;

m. Plaintiff Janice A. Lukacinsky is a citizen and resident of Whitman, MA who is suffering from VHD as a result of the ingestion of the Diet Drugs;



n. Plaintiff Sally Jane Minzey is a citizen and resident of Prescott, MI who is suffering from VHD as a result of the ingestion of the Diet Drugs;

o. Plaintiff Irma A. Ochoa is a citizen and resident of El Paso, TX who is suffering from VHD as a result of the ingestion of the Diet Drugs;

p. Plaintiff Teresa A. Shuff is a citizen and resident of Fullerton, CA who is suffering from VHD as a result of the ingestion of the Diet Drugs;

q. Plaintiff Bonnie L. Tacy is a citizen and resident of Bangor, NY who is suffering from VHD as a result of the ingestion of the Diet Drugs;

r. Plaintiff Victoria Vance is a citizen and resident of Fort Worth, TX who is suffering from VHD as a result of the ingestion of the Diet Drugs;

3. Each and every Plaintiff was prescribed and did ingest dexfenfluramine, sold under the brand name Redux™. As well, upon information and belief, some of the Plaintiffs also ingested fenfluramine, sold under both the generic name fenfluramine and the brand name Pondimin®, comprised of dexfenfluramine as its sole active ingredient.

4. Plaintiffs meet all medical criteria to qualify as intermediate and/or back-end opt-outs to the National Settlement. Specifically, Plaintiffs' echocardiograms, all of which were read and interpreted by board-certified cardiologists, demonstrate that they meet the definition of FDA positive heart valve regurgitation as defined by the National Settlement. Plaintiffs have properly exercised intermediate and/or back-end opt-out rights by completing, signing and timely submitting an opt-out form to the Settlement Court, the Trustees, and/or the Claims Administrator(s) and to the Wyeth Defendants. By filing this Complaint, Plaintiffs assert only those claims and is seeking only those damages as are permitted under the National Settlement.

No other language in this Complaint shall be interpreted as Plaintiffs' intent to do otherwise. All aspects of this action are consistent with Plaintiffs' rights as an intermediate and/or back-end opt-out from the National Class Action Settlement.

5. Each and every Plaintiff named herein has filed this lawsuit within any applicable statute of limitations period.

6. Each and every Plaintiff named herein acted with diligence in attempting to discover any injury caused by their ingestion of the Diet Drugs, including following the advise of their physicians, monitoring their symptoms, and following the recommendations of the American Medical Association, American College of Cardiology, American Heart Association, American Society of Echocardiography, United States Department of Health and Human Services, and the National Diet Drug Settlement. Such Plaintiffs did not and could not have discovered their injury until they had an echocardiogram demonstrating the presence of FDA positive valvular heart disease, and could not have brought a cause of action against any of the named Defendants, including Defendant Interneuron until such Plaintiffs discovered that any injury detected was a result of the action and/or omissions of the named Defendants, including Defendant Interneuron.

7. Any statute of limitations period which applies to the Plaintiffs' claims against Defendant Interneuron, have been tolled under the principles of class action tolling as recognized by the Appeals Court of Massachusetts in *DiCerbo v. Commissioner Of The Department Of Employment And Training*, 54 Mass.App.Ct. 128, 763 N.E.2d 566 (Mass.App.Ct. 2003), citing *American Pipe & Constr. Co. v. Utah*, 414 U.S. 538, 554, 94 S.Ct. 756, 38 L.Ed.2d 713 (1974) and *Crown, Cork & Seal Co. v. Parker*, 462 U.S. 345, 353-354, 103 S.Ct. 2392, 76 L.Ed.2d 628

(1983), as multiple class actions against Interneuron have been filed in state and federal courts across the country, bringing claims which are substantially the same as those claims brought in this lawsuit, including the class action complaint, *Doherty et al. v. Interneuron, et al*, No. 98-0028-C, filed in Massachusetts state court in 1998 and which remained pending through the summer of 2001. Any effort by Defendant Wyeth to remove this case based on the principle of the fraudulent joinder of Defendant Interneuron is, therefore, an improvident removal, done solely to deprive Plaintiffs of their right to bring their claims in the forum of their choice.

### **Introduction**

8. The Diet Drugs which Plaintiffs were prescribed and ingested, and which caused Plaintiffs to suffer valvular heart disease and associated injuries, were defective and unreasonably dangerous in that the Diet Drugs: were not reasonably safe for their intended use as a weight loss drugs; subjected Plaintiffs to risks which exceeded the benefits of the Diet Drugs, if any; were defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect; were more dangerous than other risks associated with obesity and/or weight loss; and were otherwise defective and unreasonably dangerous as set forth herein.

9. The defective and unreasonably dangerous Diet Drugs caused Plaintiffs to suffer from valvular heart disease and resultant injuries and damages. Valvular heart disease ("VHD") is a serious and potentially fatal disease marked by the improper backward flow or "regurgitation" of blood within in the heart's chambers and blood vessels caused by the failure of the heart's valves, which separate the heart's chambers, from properly closing. When the heart's valves fail to close sufficiently, a common result of Diet Drug ingestion, this causes the regurgitation of blood back into the chamber from which it has been pumped altering the

hemodynamics within the heart. Such regurgitation is a progressive condition causing the heart to work harder to supply the body with adequate blood and oxygen. As the heart muscle is forced to over-work, physiological and morphological changes occur whereby the heart muscle becomes enlarged and distorted in shape. As a consequence, conditions and injuries suffered as a result of these and similar Diet Drug induced changes in the heart include but are not limited to: congestive heart failure, pulmonary hypertension, valve replacement surgery, and/or death.

10. Before the Plaintiffs were prescribed and ingested the Diet Drugs which caused them to suffer VHD and associated injuries, Defendants knew or should have known that the Diet Drugs had been related to and associated with these serious and life threatening side effects. The Defendants had an obligation under the law to disclose the association between their products and VHD.

11. Due to Defendants' failure to adequately warn the FDA and doctors prescribing the Diet Drugs of the known risks of VHD, Plaintiffs' physicians were unable to inform Plaintiffs of the true risks associated with the ingestion of the Diet Drugs including VHD. These side effects were known or should have been known to Defendants at the time that they marketed the drugs to the public based on, among other things, adverse event reports, clinical studies and the medical evidence of dangerous and potentially fatal side effects from the use of the drugs in Europe and elsewhere. Defendants did not, however, conduct adequate testing to establish the safety of the drugs before marketing them nor did Defendants perform adequate post-marketing surveillance and monitoring which would have otherwise prevented Plaintiffs' injuries. Rather, the Defendants through their marketing and promotional campaigns downplayed and/or

obfuscated evidence of the serious and potentially fatal side effects that consumers of these drugs could face.

### Defendants

12. The Defendant, Indevus Pharmaceuticals, Inc., f/k/a Interneuron Pharmaceuticals, Inc. ("Interneuron") has its principal place of business at the Ledgemont Center, 99 Hayden Avenue, Lexington, Massachusetts and is incorporated in the State of Delaware. At all times relevant hereto, Interneuron was engaged in the business of researching, formulating, testing, developing, designing, licensing, assembling, compounding, marketing, promoting, distributing, detailing, and/or selling the pharmaceutical diet drug Redux. At all times relevant hereto, Interneuron researched, formulated, tested, developed, designed, licensed, assembled, compounded, marketed, promoted, distributed, detailed, and/or sold Redux through interstate commerce through the use of its employees and/or agents including Interneuron's field sales representative force or detailers who made direct contact with physicians including Plaintiffs' prescribing doctors. Beginning in or about 1989, Interneuron researched, created, formulated, tested, developed, designed, and/or licensed Redux. On or about November 19, 1992, Interneuron entered into a joint venture or partnership with American Cyanamid Company ("American Cyanamid" or "Wyeth Defendants"), a predecessor company to the Wyeth Defendants, and Les Laboratories Servier ("Servier") pursuant to the terms of a "Patent and Know-How Sublicense Supply Agreement" for the manufacturing, marketing, labeling, promotion and sale of Redux. On or about November 21, 1995, Defendant, Interneuron, entered into an exclusive "Contract Manufacturing Agreement" with Defendant, Boehringer, by which Boehringer agreed to manufacture, develop, test, assemble, package, label, prepare and/or supply



Redux exclusively for and/or to Defendant, Interneuron, including supplying Defendant, Interneuron, with all of its requirements of Redux for ultimate sale in the United States including the State of Massachusetts. On or about June 1, 1996, Interneuron entered into a "Co-promotion Agreement" with the Wyeth Defendants which both reaffirmed the pre-existing joint venture or partnership between Interneuron and the Wyeth Defendants and provided for Interneuron to market, promote, advertise, distribute, label, detail, supply, package and/or sell Redux in consideration for the payments from Interneuron's co-promoter, Wyeth Defendants, for percentages of profit derived from sales generated by Interneuron's sales representative sales force. At all times material hereto, Interneuron does and did business in the State of Massachusetts and researched, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold the pharmaceutical known as Redux in interstate commerce and in the various States within which Plaintiffs were prescribed and ingested the Diet Drugs.

13. The Defendant, Wyeth, Inc., f/k/a American Home Products Corporation, is a Delaware corporation with its principal place of business at 5 Giralda Farms, Madison, New Jersey. At all times material hereto, this Defendant manufactured, supplied, packaged, labeled, detailed promoted, advertised, marketed, distributed and/or sold the pharmaceuticals known as Pondimin and Redux. A.H. Robins Company, Incorporated ("A.H. Robins") was a corporation, organized and existing under the laws of the State of Delaware, which manufactured, supplied, packaged, labeled, detailed promoted, advertised, marketed, distributed and/or sold Pondimin for many years between 1973 and 1990. A.H. Robins had its principal place of business in the State

of Virginia until at least 1990, when it was acquired by American Home Products Corporation, now known as Wyeth, which company has assumed all responsibility for any liability of A.H. Robins arising from its manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Pondimin. On or about November 19, 1992, Wyeth, Inc., through another predecessor company, American Cyanamid, whose assets and liabilities it later acquired, entered into a joint venture or partnership with Interneuron Pharmaceuticals, Inc. and Servier pursuant to the terms of a "Patent and Know-How Sublicense Supply Agreement" for the manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Redux and at all times material was engaged in a joint venture or partnership with Interneuron Pharmaceuticals, Inc., Servier, and Boehringer Ingelheim, Inc., in the manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Redux. On or about June 1, 1996, this Defendant entered into a "Co-promotion Agreement" with Interneuron Pharmaceuticals, Inc. that reaffirmed the joint venture or partnership between this Defendant and Interneuron Pharmaceuticals, Inc. At all times material hereto, this Defendant does and did business in the State of Massachusetts and researched, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold the pharmaceutical known as Pondimin and Redux in interstate commerce and in the various States within which Plaintiffs were prescribed and ingested the Diet Drugs.

14. The Defendant, Wyeth Pharmaceuticals, f/k/a Wyeth-Ayerst Laboratories, Inc., is a Delaware Corporation with its principal place of business at 500 Arcola Drive, Collegeville,

Pennsylvania. At all times material hereto, this Defendant manufactured, supplied, packaged, labeled, detailed promoted, advertised, marketed, distributed and/or sold the pharmaceuticals known as Pondimin and Redux. A.H. Robins was a corporation, organized and existing under the laws of the State of Delaware, which manufactured, supplied, packaged, labeled, detailed promoted, advertised, marketed, distributed and/or sold Pondimin for many years between 1973 and 1990. A.H. Robins had its principal place of business in the State of Virginia until at least 1990, when it was acquired by American Home Products Corporation, now known as Wyeth, which company has assumed all responsibility for any liability of A.H. Robins arising from its manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Pondimin. On or about November 19, 1992, Wyeth, Inc., through another predecessor company, American Cyanamid, whose assets and liabilities it later acquired, entered into a joint venture or partnership with Interneuron Pharmaceuticals, Inc. and Servier pursuant to the terms of a "Patent and Know-How Sublicense Supply Agreement" for the manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Redux and at all times material was engaged in a joint venture or partnership with Interneuron Pharmaceuticals, Inc., Servier, and Boehringer Ingelheim, Inc., in the manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Redux. On or about June 1, 1996, this Defendant entered into a "Co-promotion Agreement" with Interneuron Pharmaceuticals, Inc. that reaffirmed the joint venture or partnership between this Defendant and Interneuron Pharmaceuticals, Inc. At all times material hereto, this Defendant does and did business in the State of Massachusetts and researched, created, formulated, tested, developed, designed, licensed, assembled, compounded,

manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold the pharmaceutical known as Pondimin and Redux in interstate commerce and in the various States within which Plaintiffs were prescribed and ingested the Diet Drugs.

15. The Defendant, Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer"), is a Delaware Corporation with its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877. At all times material hereto, this Defendant was in the business of manufacturing, assembling, developing and/or supplying the pharmaceutical known as Redux. On or about November 21, 1995, Defendant, Boehringer, entered into an exclusive "Contract Manufacturing Agreement" with Defendant, Interneuron, by which Boehringer agreed to manufacture, develop, test, assemble, package, label, prepare and/or supply Redux exclusively for and/or to Defendants, Interneuron and Wyeth Defendants, including supplying Defendants Interneuron and the Wyeth Defendants, with all of its requirements of Redux for sale in the United States. At all times material hereto, Boehringer does and did business in Massachusetts and manufactured, developed, tested, assembled, packaged, labeled, prepared and/or supplied Redux in interstate commerce and in the various States within which Plaintiffs were prescribed and ingested the Diet Drugs. Upon information and belief, the Redux ingested by Plaintiffs was manufactured, developed, tested, assembled, packaged, labeled, prepared and/or supplied by Boehringer. Though "Diet Drugs" as provided herein shall otherwise include both Redux and Pondimin, all allegations referencing "Diet Drugs" as set forth herein relating to Boehringer shall only relate to Redux.

16. The sales representatives were responsible for detailing Interneuron, Boehringer, and Wyeth products to prescribing physicians. In detailing, these representatives presented drugs

to physicians and explained efficacy, side effects, and any warnings related to the drug. These defendants knew or should have known at the time of drug approval, or through post-marketing surveillance, the risks of heart and lung disease associated with the use of Pondimin and Redux and that these drugs were ineffective and unproven for long-term weight control. These defendants also had first-hand knowledge that Pondimin and Redux were being widely used. These defendants had the responsibility to inform physicians about these risks. Nonetheless, these representatives failed and neglected to warn physicians or consumers of these dangers. These defendants are responsible for their own acts of negligence or otherwise tortious conduct with respect to the marketing of Interneuron, Boehringer, and Wyeth products.

17. The Defendant, Robert R. DeCapua, an individual, is a citizen and resident of Rowlett, Texas and can be served at 5250 Grisham, Rowlett, Texas 75088. Defendant Robert R. DeCapua is sued as a sales representative solely as to the claims of Plaintiff Carla S. Alvanchi.

18. The Defendant, Justin D. Crum, an individual, is a citizen and resident of Irving, Texas and can be served at 9827 N. MacArthur, Apt. 1304, Irving, Texas, 75063. Defendant Justin D. Crum is sued as a sales representative solely as to the claims of Plaintiff Carla S. Alvanchi.

19. The Defendant, Bernice J. Menzies, an individual, is a citizen and resident of Dallas, Texas and can be served at 7019 Claybrook, Dallas, Texas 75231. Defendant Bernice J. Menzies is sued as a sales representative solely as to the claims of Plaintiff Carla S. Alvanchi.

20. The Defendant, Larry D. Bayliff, an individual, is a citizen and resident of Highland Park, Illinois and can be served at 765 St. Johns Avenue, Highland Park, Illinois



60035. Defendant Larry D. Bayliff is sued as a sales representative solely as to the claims of Plaintiff Vickie L. Beinlich.

21. The Defendant, Michelle L. Carner, an individual, is a citizen and resident of Palatine, Illinois and can be served at 223 W. Slade Street, Palatine, Illinois 60067. Defendant Michelle L. Carner is sued as a sales representative solely as to the claims of Plaintiff Vickie L. Beinlich.

22. The Defendant, Gerald E. Lubben an individual, is a citizen and resident of McHenry, Illinois and can be served at 4740 Loyola Drive, McHenry, Illinois 60050-0511. Defendant Gerald E. Lubben is sued as a sales representative solely as to the claims of Plaintiff Vickie L. Beinlich.

23. The Defendant, Joseph Schrei an individual, is a citizen and resident of Cary, Illinois and can be served at 1110 Patriot Lane, Cary, Illinois 60013. Defendant Joseph Schrei is sued as a sales representative solely as to the claims of Plaintiff Vickie L. Beinlich.

24. The Defendant, Gail S. Rasak an individual, is a citizen and resident of Livonia, Michigan and can be served at 11034 Berwick, Livonia, Michigan 48150. Defendant Gail S. Rasak is sued as a sales representative solely as to the claims of Plaintiff Cynthia D. Cargile.

25. The Defendant, Marlo F. Ponos (a/k/a Marlo F. Tate) an individual, is a citizen and resident of South Lyon, Michigan and can be served at 932 S. Parkwood, South Lyon, Michigan 48178. Defendant Marlo F. Ponos (a/k/a Marlo F. Tate) is sued as a sales representative solely as to the claims of Plaintiff Cynthia D. Cargile.

26. The Defendant, Gregory Fountain an individual, is a citizen and resident of Gahanna, Ohio and can be served at 423 Whitley Drive, Gahanna, Ohio 43230. Defendant

Gregory Fountain is sued as a sales representative solely as to the claims of Plaintiff Terry Robert Gabrich, Sr.

27. The Defendant, Michael D. Zell an individual, is a citizen and resident of Westerville, Ohio and can be served at 78 Hampton Park, E., Westerville, Ohio 43081. Defendant Michael D. Zell is sued as a sales representative solely as to the claims of Plaintiff Terry Robert Gabrich, Sr.

28. The Defendant, Lyn A. Adanich an individual, is a citizen and resident of N. Royalton, Ohio and can be served at 7642 Wilton Lane, N. Royalton, Ohio. Defendant Lyn A. Adanich is sued as a sales representative solely as to the claims of Plaintiff Robert John Golia.

29. The Defendant, Mary Ann Roberts an individual, is a citizen and resident of N. Royalton, Ohio and can be served at 375 Highland Avenue, N. Royalton, Ohio 44133. Defendant Mary Ann Roberts is sued as a sales representative solely as to the claims of Plaintiff Robert John Golia.

30. The Defendant, Kathleen A. Welsh an individual, is a citizen and resident of N. Royalton, Ohio and can be served at 9891 Dublin Drive, N. Royalton, Ohio 44133. Defendant Kathleen A. Welsh is sued as a sales representative solely as to the claims of Plaintiff Robert John Golia.

31. The Defendant, Ronald L. Duemler an individual, is a citizen and resident of Wyoming, Michigan and can be served at 1611 Chateau Drive, Wyoming, Michigan 49509. Defendant Ronald L. Duemler is sued as a sales representative solely as to the claims of Plaintiff Camille Denice Johnson.

32. The Defendant, Dennis M. Thimm an individual, is a citizen and resident of

Zeeland, Michigan and can be served at 6121 Prairie, Zeeland, Michigan 44281. Defendant Dennis M. Thimm is sued as a sales representative solely as to the claims of Plaintiff Camille Denice Johnson.

33. The Defendant, Lance E. Reno an individual, is a citizen and resident of Mentor, Ohio and can be served at 7971 Stockbridge Road, Mentor, Ohio 44060. Defendant Lance E. Reno is sued as a sales representative solely as to the claims of Plaintiff Edith A. Guffey.

34. The Defendant, Cynthia M. Cowgill an individual, is a citizen and resident of Lexington, Kentucky and can be served at 279 Cassidy Avenue, Lexington, Kentucky 40502. Defendant Cynthia M. Cowgill is sued as a sales representative solely as to the claims of Plaintiff Lisa Henkel.

35. The Defendant, Timothy S. Circle an individual, is a citizen and resident of Ripley, West Virginia and can be served at 110 Batton Drive, Ripley, West Virginia 25271. Defendant Timothy S. Circle is sued as a sales representative solely as to the claims of Plaintiff Sherry L. Jackson.

36. The Defendant, Donell N. Henthorne an individual, is a citizen and resident of Parkersburg, West Virginia and can be served at 301 Palmer Drive, Parkersburg, West Virginia 26104. Defendant Donell N. Henthorne is sued as a sales representative solely as to the claims of Plaintiff Sherry L. Jackson.

37. The Defendant, Melody Phillips-Williams an individual, is a citizen and resident of Parkersburg, West Virginia and can be served at 44 Oak Circle, Parkersburg, West Virginia 26101. Defendant Melody Phillips-Williams is sued as a sales representative solely as to the claims of Plaintiff Sherry L. Jackson.

38. The Defendant, Steve Sneider an individual, is a citizen and resident of Dallas, Texas and can be served at 4849 Frankford Road, Apt. 1026, Dallas, Texas 75287. Defendant Steve Sneider is sued as a sales representative solely as to the claims of Plaintiff Linda Marlene Johnson.

39. The Defendant, Richard A. Dilibero an individual, is a citizen and resident of Cranston, Rhode Island and can be served at 71 Arrow Way, Cranston, Rhode Island 02921. Defendant Richard A. Dilibero is sued as a sales representative solely as to the claims of Plaintiff Linda S. Kennelly.

40. The Defendant, Thomas M. Duggan an individual, is a citizen and resident of Franklin, Massachusetts and can be served at 103 E. Central Street, Franklin, Massachusetts 02038. Defendant Thomas M. Duggan is sued as a sales representative solely as to the claims of Plaintiff Linda S. Kennelly.

41. The Defendant, John Doe, an individual, is sued as a sales representative solely as to the claims of Plaintiff Linda S. Kennelly.

42. The Defendant, Jennifer Hetherington an individual, is a citizen and resident of Midland, Michigan and can be served at 2342 Spruce Ridge Drive, Midland, Michigan 48642. Defendant Jennifer Hetherington is sued as a sales representative solely as to the claims of Plaintiff Sally Jane Minzey.

43. The Defendant, Joanne M. Izykowski an individual, is a citizen and resident of Bay City, Michigan and can be served at 4678 Birchwood Drive, Bay City, Michigan 48438. Defendant Joanne M. Izykowski is sued as a sales representative solely as to the claims of Plaintiff Sally Jane Minzey.

44. The Defendant, Zoanne Pokriefka an individual, is a citizen and resident of Goodrich, Michigan and can be served at 8364 Ridge Road, Goodrich, Michigan 48438. Defendant Zoanne Pokriefka is sued as a sales representative solely as to the claims of Plaintiff Sally Jane Minzey.

45. The Defendant, Joseph DiFrancesco an individual, is a citizen and resident of Phoenix, Arizona and can be served at 1724 East Cathedral Rock, Phoenix, Arizona 85048. Defendant Joseph DiFrancesco is sued as a sales representative solely as to the claims of Plaintiff Irma Ochoa.

46. The Defendant, Hope Tileston an individual, is a citizen and resident of San Diego, California and can be served at 7101 Teasdale Avenue, San Diego, California 92122. Defendant Hope Tileston is sued as a sales representative solely as to the claims of Plaintiff Irma Ochoa.

47. The Defendant, Thomas A. Wiehn an individual, is a citizen and resident of Glendale, Arizona and can be served at 22720 N. 74th Drive, Glendale, Arizona 85310. Defendant Thomas A. Wiehn is sued as a sales representative solely as to the claims of Plaintiff Irma Ochoa.

48. The Defendant, Lisa M. Birken (a/k/a Lisa Greenbaum) an individual, is a citizen and resident of Seal Beach, California and can be served at 920 Mar Vista Avenue, Seal Beach, California 90740. Defendant Lisa M. Birken (a/k/a Lisa Greenbaum) is sued as a sales representative solely as to the claims of Plaintiff Teresa Shuff.

49. The Defendant, Shonda S. Shores (a/k/a Shonda S. Kim) an individual, is a citizen and resident of Brea, California and can be served at 858 E. Buchanan Court, Brea, California



92821. Defendant Shonda S. Shores (a/k/a Shonda S. Kim) is sued as a sales representative solely as to the claims of Plaintiff Teresa Shuff.

50. The Defendant, Christian K. Miner an individual, is a citizen and resident of Fairfax, Vermont and can be served at 1112 Main Street, Fairfax, Vermont 05454. Defendant Christian K. Miner is sued as a sales representative solely as to the claims of Plaintiff Bonnie L. Tacy.

51. The Defendant, Kimberly Ann Owen an individual, is a citizen and resident of Henderson, New York and can be served at 15254 Snowshoe Road, Henderson, New York 13650. Defendant Kimberly Ann Owen is sued as a sales representative solely as to the claims of Plaintiff Bonnie L. Tacy.

52. The Defendant, Mary M. Bodenhamer an individual, is a citizen and resident of Fort Worth, Texas and can be served at 6418 Lago Vista, Fort Worth, Texas 76132. Defendant Mary M. Bodenhamer is sued as a sales representative solely as to the claims of Plaintiff Victoria Vance.

53. The Defendant, Alicia I. McDougal an individual, is a citizen and resident of Fort Worth, Texas and can be served at 2465 Jefferson Court Lane, Fort Worth, Texas 76006. Defendant Alicia I. McDougal is sued as a sales representative solely as to the claims of Plaintiff Victoria Vance.

54. The Defendant, Shannon O. Sage an individual, is a citizen and resident of Fort Worth, Texas and can be served at 5401 Overton Ridge Blvd., Apt. 2503, Fort Worth, Texas 76132. Defendant Shannon O. Sage is sued as a sales representative solely as to the claims of Plaintiff Victoria Vance.

### **Factual Background**

55. Aminorex, discovered in 1960 by United States pharmaceutical company, McNeil Laboratories, was a drug from the same family of drugs as fenfluramine and dexfenfluramine. Aminorex was touted as a wonder weight loss drug which, like fenfluramine and dexfenfluramine, worked by increasing brain serotonin while inhibiting reuptake of serotonin.

56. Fenfluramine is made up of two “mirror image” halves or isomers: dexfenfluramine (right-handed isomer or d-isomer), the isomer which increases the release and prevents the reuptake of serotonin in the brain, thereby presumably reducing appetite, and levofenfluramine (left-handed isomer or l-isomer), which increases dopamine release but can cause the unwanted side-effect of drowsiness.

57. In 1963, Science Union & Co., an affiliate of Servier, entered into a licensing agreement with Wyeth Defendants’ predecessor, A.H. Robins, giving it the right to market, promote, distribute, detail, sell or otherwise profit from the sale of fenfluramine in the United States.

58. In 1965, after securing authorization for the marketing of fenfluramine in Europe, Servier commenced the sale of products containing fenfluramine in Europe. This same year, Aminorex was introduced into the European market.

59. However, by 1967, evidence began to surface that the ingestion of Aminorex was associated with pulmonary hypertension. Over the next five years, Aminorex caused in Europe a ten-fold increase in pulmonary hypertension cases, permanent injury to patients who suffered significant oxygen deprivation, and numerous deaths. In light of the reports of Aminorex induced pulmonary hypertension, McNeil Laboratories prudently suspended its research and

efforts to bring Aminorex to the United States market. By 1972, Aminorex was removed from the European market.

60. In or about 1970, during the European experience, Dr. Richard Wurtman, a faculty member of the Massachusetts Institute of Technology (MIT) and the founder of Interneuron secured a United States patent for use of fenfluramine as a diet drug. Like Aminorex, Fenfluramine was touted as a wonder weight loss drug designed to effect weight loss by increasing brain serotonin while inhibiting reuptake of serotonin. The patent and rights to market fenfluramine as an obesity drug were thereafter sub-licensed by Dr. Wurtman and/or MIT to Servier.

61. Despite the European experience, in June of 1973, fenfluramine was introduced into the United States market by A.H. Robins which sold fenfluramine under the brand name Pondimin. However, after introduction into the United States market, sales of fenfluramine languished both because of restrictions in prescribing under the Controlled Substance Act and because the fenfluramine isomer levofenfluramine caused users to become lethargic and tired when using Pondimin alone.

62. In 1977, Finnish researchers found a causal link between fenfluramine/dexfenfluramine and heart valve lesions. Based on a study of weight-loss drugs including Aminorex and fenfluramine/dexfenfluramine and their effects on the release of serotonin, it was discovered that not only was the concentration of free serotonin in the blood vessels of the lungs caused by the weight-loss drug responsible for pulmonary hypertension, but also that the vessel wall-thickening mechanism which caused pulmonary hypertension was likely the identical mechanism which caused right-sided heart valve thickening and regurgitation in carcinoid

patients.

63. Recognizing the problems in selling fenfluramine caused by the levofenfluramine isomer which caused users to become lethargic and tired, in or about 1980, Servier discovered a commercially feasible way to chemically isolate and separate the active ingredient in fenfluramine, being the right-sided d-isomer (dexfenfluramine) from the undesirable left-sided isomer (levofenfluramine) and commissioned and/or contracted Dr. Wurtman and/or MIT to further research, formulate, test, develop, design, license, assemble, compound, manufacture, market, promote, advertise, distribute, label, detail, supply, package and/or sell Redux for the United States market. This same year, MIT and/or Dr. Wurtman, secured a United States patent for use of dexfenfluramine as an obesity drug and thereafter, as with fenfluramine a decade earlier, sub-licensed the patent back to Servier.

64. On October 3, 1981, Dr. J.G. Douglas published *Pulmonary Hypertension and Fenfluramine* in the British Medical Journal. On January 25, 1986 an article entitled *Irreversible Pulmonary Hypertension after Treatment with Fenfluramine*, was published in the British Medical Journal. Defendants knew, or should have known, of the British Medical Journal articles and how those articles related to fenfluramine and dexfenfluramine, and their propensity to cause valvular heart disease, and secondary pulmonary hypertension.

65. While the sales of Pondimin languished between 1973 and 1984, sales of Pondimin increased, however, after several studies or reports sponsored, subsidized, and/or supported by the Wyeth Defendants' predecessor, A.H. Robins, were published within the medical community. Specifically, in 1984, Dr. Michael Weintraub published *A Double-Blind Clinical Trial in Weight Control: Use of Fenfluramine and Phentermine Alone and in*

*Combination* in the Archives of Internal Medicine. Dr. Weintraub's study was sponsored, subsidized, and/or supported by A.H. Robins (later acquired by the Wyeth Defendants). Despite noting some adverse effects associated with fenfluramine, Dr. Weintraub failed to examine the long-term safety of fenfluramine. Instead, the study focused on the short-term effectiveness of the drugs used individually, and in combination with phentermine.

66. In 1985, after securing authorization for the marketing of dexfenfluramine in Europe, Servier commenced the sale of products containing dexfenfluramine in Europe under the brand/trade names Adifax (in England) and Isomeride (in France).

67. In or about 1989, after MIT and Dr. Wurtman had researched, formulated, tested, developed, designed, licensed, assembled and compounded dexfenfluramine for several years in preparation for submitting dexfenfluramine for FDA approval and licensing for sale in the United States, Dr. Wurtman incorporated Defendant, Interneuron.

68. In or about 1990, Servier sub-licensed the rights to market, promote, distribute, detail, sell or otherwise profit from the sale of dexfenfluramine in the United States back to Interneuron.

69. On or about February 27, 1990, representatives from Interneuron, Wyeth Defendants and Servier convened to discuss "certain situations pertaining to Pondimin", including protocols and respective responsibilities relating to adverse event reporting and safety information, during which Servier representatives Madame Derome-Tremblay and Christine Bazantay advised the Wyeth Defendants that there was a need to update the 1972 labeling for Pondimin. However, there was no change in the labeling of Pondimin between 1990 and mid-1996.



70. In September of 1990, Servier, co-licensor of both Pondimin and Redux in coordination with Interneuron and the Wyeth Defendants, completed a study regarding the effects of fenfluramine isomers on Fisher Rats which showed significant levels of focal fibrosis in the hearts of rats treated with doses of dexfenfluramine as compared with hearts of untreated rats. Defendants knew or should have known of the Fisher Rat study and how those articles related to fenfluramine and dexfenfluramine. At the very least, Interneuron and the Wyeth Defendants knew or should have known of the results of the Fisher Rat study by March 19, 1992, the date that the study was released by Servier.

71. On March 18, 1991, Interneuron, filed a petition with the DEA requesting that fenfluramine and its isomer dexfenfluramine be removed from Schedule IV and all other controls of the Controlled Substances Act (CSA) such that, among other things, both Pondimin and Redux could be dispensed and prescribed in larger quantities and over longer incremental dosage durations. Interneuron's efforts to gain the de-scheduling of both fenfluramine and dexfenfluramine, continued by using politicians and large anti-regulatory political action committees aimed at persuading both the DEA and FDA.

72. On or about October 25, 1991, Interneuron, through the assistance of Cato Research, Ltd. filed an Investigational New Drug Application with the FDA in furtherance of securing approval for Redux.

73. In 1992, Dr. Weintraub again published a series of articles sponsored, subsidized, and/or supported by the Wyeth Defendants in *Clinical Pharmacological Therapies*, in which he reported his research regarding the long term use of fenfluramine and phentermine for weight control. Dr. Weintraub's research assumed the safety of fenfluramine, and did not examine the

short-term or long-term safety of the drug. The Wyeth Defendants failed to conduct or fund any studies or research regarding the long-term safety of the fenfluramine. The Wyeth Defendants, and later Interneuron, through their sales representative force, promoted Dr. Weintraub's conclusion that long term combination use of fenfluramine and phentermine was effective for the management of obesity to both physicians, and the public. As a result, sales of Pondimin began to increase dramatically.

74. On or about November 19, 1992, Interneuron entered into a joint venture or partnership with American Cyanamid, a predecessor company to the Wyeth Defendants, and Servier pursuant to the terms of a "Patent and Know-How Sublicense Supply Agreement" for the manufacturing, marketing, labeling, promotion and sale of Redux.

75. On or about April 15, 1993, Interneuron and Wyeth Defendants, through their employees, agents and/or representative parties, including Dr. Bobby W. Sandage, Jr., Interneuron's Vice-President of Research and Development and employees Dukart, Hammershaimb, Gantt, Lefkowitz, Stout and Quinn of Wyeth Defendants, met with Dr. Stuart Rich, Section of Cardiology at University of Illinois at Chicago, an expert in the area of pulmonary hypertension ("PH"), to discuss the cases of PH reported following the use of Redux and "to help put this information into perspective." Interneuron and Wyeth Defendants at this time recognized Dr. Rich as a Principal Investigator and member of the steering committee for the NIH Registry for the Characterization of PH who had reviewed approximately thirty-six (36) cases of the drug relationship between Redux and PH and further admitted that there was an association between PH and the intake of certain exogenous substances such as and including Redux. Dr. Rich advised Interneuron and Wyeth Defendants that there was an increased risk for

PH which necessitated caution until more definitive information was available. This information placed or should have placed the Defendants on notice of the association between the Diet Drugs and pulmonary hypertension, and that pulmonary hypertension may be related to valvular heart disease.

76. By 1993, the Wyeth Defendants labeling for Pondimin indicated that there were only 4 reported cases of pulmonary hypertension reported in association with the drug. Yet, that same year, Dr. Francois Brenot published an article related to the association of Fenfluramine and pulmonary hypertension, in the British Heart Journal. Dr. Brenot identified 25 cases of pulmonary hypertension associated with the use of fenfluramine and/or dexfenfluramine. The Wyeth Defendants knew or should have known of the Brenot article. The Wyeth Defendants should have known by at least 1993 that Pondimin was defective and unreasonably dangerous and further that its Pondimin labeling was false.

77. On or about May 21, 1993, Interneuron filed its NDA with the FDA for the approval of Redux. In its bid for FDA's Redux approval, Interneuron and Wyeth Defendants relied upon several pivotal "studies" in its NDA, including but not limited to, the Noble Study, the Van Itallie Study, and the Index Study.

78. Interneuron and Wyeth Defendants knew at the time of submitted the NDA for Redux to the FDA that these pivotal studies were flawed, defective and substandard, thereby effecting misrepresentations to the FDA, the medical community, Plaintiffs' prescribing physicians and Plaintiffs. In particular, Interneuron and Wyeth Defendants were on notice through advice by Interneuron's own auditor, Bruce Sturgeon (such internal audits being typically required and expected of NDA applicants), both before and during the NDA submission

and subsequent supportive documentation, that:

- a. the Noble Study had careless record keeping, several protocol violations, a lack of documentation for final disposition of the drug and missing progress reports to the IRB;
- b. the Van Itallie Study, which Mr. Sturgeon concluded would probably not be accepted by the FDA – though Interneuron still included the same in its NDA — included a protocol change increasing the allowable weight fluctuation from 3 kilograms to 7.5 percent of body weight without notifying the IRB or FDA, thereby reflecting a gross deviation from good clinical practices; used three patients who did not meet the revised criteria for the study; and contained inaccurate drug accountability for all patients, exacerbated by the fact that the drug was a controlled substance; and
- c. the Index Study was poorly monitored, lacked proper and complete documentation, contained high error incidents in key data reporting found across all sites, and suffered from poor data quality consistent among all sampled sites which could be extrapolated to all sites in the Index Study.

79. During the time Interneuron filed its NDA for Redux, Interneuron and Wyeth Defendants knew or should have known that there were serious health risks associated with Redux which were neither sufficiently nor adequately expressed in either its NDA or its 120 Day Update.

80. By 1993, nearly two decades after the 1977 Finnish study, numerous medical reports and studies had been published within mainstream medical journals and publications firmly establishing the same causal connection between high concentrations of free circulating serotonin, as caused by fenfluramine and dexfenfluramine, and heart valve lesions, including but not limited to: Ann Redfield MM, Nicholson WJ, Edwards WD, Tajik AJ. *Valve disease associated with ergot alkaloid use: echocardiographic and pathologic correlations*. Ann Intern Med 1992;117:50-52; and Pellikka PA, Tajik AJ, Khandheria BK, et al. *Carcinoid heart disease: clinical and echocardiographic spectrum in 74 patients*. Circulation 1993;87:1188-96. As reaffirmed by these medical journal publications and their long and numerous progeny

spanning nearly three decades, there was an available body of scientific knowledge identifying the pharmacologic affects of various anorexic agents, including fenfluramine and dexfenfluramine, on circulating (release, reuptake inhibition and monoamine oxidase inhibition) serotonin. Moreover, there was an available body of scientific knowledge relating elevations in serotonin as found in ergotamine toxicity and carcinoid syndrome, like fenfluramine and dexfenfluramine, to incidents of VHD. During this period of time in which Interneuron and the Wyeth Defendants were proceeding with the Redux NDA and while the Wyeth Defendants continued to sell Pondimin on the United States market, Interneuron and Wyeth Defendants knew or should have known that fenfluramine and dexfenfluramine caused an increase in circulating serotonin and that a serotonin-related mechanism was directly associated with VHD. Interneuron and Wyeth Defendants failed to disclose the connection between the Diet Drugs and VHD and/or failed to perform pre-marketing studies and post-marketing surveillance which would have detected this fact.

81. In or about 1994, cases of heart valve damage from the use of the Diet Drugs began to appear throughout the Country including sonographer, Pamela Ruff's discovery in Fargo, North Dakota of VHD in patients who had ingested Pondimin. Numerous cases of Diet Drug induced VHD prompted physicians at the Mayo Clinic to undertake a case review which ultimately resulted in the untimely forced withdrawal of the Diet Drugs from the market.

82. In February 1994, the preliminary results of the International Primary Pulmonary Hypertension study ("IPPH Study") entitled "Appetite Suppressants and the Risk of Primary Pulmonary Hypertension" was released and available to the Defendants. The preliminary results of the IPPH Study confirmed the association between fenfluramine and dexfenfluramine and